

Remarks

Claims 1-4, 6-10, 12-15, 17-22, 24 and 25 are pending in the application. Claims 17-18, and 25 have been withdrawn from consideration due to the Examiner's previous restriction requirement. Claims 5, 11, 16 and 23 had been canceled in a previous reply. Applicants thank the Examiner for the withdrawal of the various objections to the claims and the rejection of the claims as not enabled under 35 U.S.C. § 112, first paragraph. Applicants reserve the right to file divisional and continuing applications directed to the subject matter of any claim withdrawn, cancelled or amended for any reason. Applicants do not acquiesce to the propriety of any of the Examiner's prior rejections and does not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 USPQ.2d 1865 (US 1997).

I. Claim Rejections under 35 U.S.C. § 103

To maintain a proper rejection under 35 U.S.C. § 103, the Examiner must meet four conditions to establish a *prima facie* case of obviousness. First, the Examiner must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Examiner must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Examiner must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). 550 U.S. ____ (2007); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each

of its elements was, independently, known in the prior art." *Id.* citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966).

A. Sheriff in View of Herzog – Claims 1, 3-7, 9-12, 14 and 16

Claims 1, 3-7, 9-12, 14 and 16 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Sheriff et al., Reg. Pept. 75-76: 309-318, 1998 ("Sheriff") in view of Herzog et al., PNAS 89: 5794-5798, 1992 ("Herzog"), "for reasons of record in the Office Action dated 17 April 2008." OA, page 3. Applicants respectfully traverse for the reasons set forth herein and the reasons set forth in their reply dated July 17, 2008, which is hereby incorporated by reference.

In response to the Applicants' arguments regarding Sheriff, the Examiner states that Sheriff demonstrates "that the luciferase activity in control cells treated with NPY but not with forskolin is not significantly different from the activity elicited by control cells that are not treated with either forskolin or with NPY." OA, page 4. Applicants contend that this interpretation is simply not grounded in anything but the Examiner's own improper independent analysis of the data presented in Sheriff. Moreover and as previously stated, Sheriff does characterize the results that way. Instead, Sheriff notes that "[a]ll three effectors, forskolin, thapsigargin and NPY, increased luciferase activity within 4 hr of treatment. . . . NPY-induced luciferase activity ranged from 1.8- to 4-fold. The induction of CRE binding and luciferase activity by NPY in SK-N-BE2 cells may involve more than one member of CRE binding transcription factors mediating this effect." Sheriff, page 313, Column 2. Thus, the Examiner's interpretation of these results is not grounded in the prior art and is contrary to the interpretation by the authors of Sheriff themselves. For these reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of Claims 1, 3-7, 9-12, 14 and 16 as obvious over Sheriff in view of Herzog.

The Examiner also rejects the Applicants' arguments that the cited art does not teach or suggest a testing "a plurality of test compounds." Specifically, the Examiner responds, stating: "it is taught in the Sheriff paper that NPY exerts several biological and cognitive functions . . . by activating the CREB pathway. Additionally, as evidenced by Impey et al., 'CREB is a key regulator of long-term memory consolidation.'" OA, page 5. From these innocuous statements, the Examiner concludes that the "person of ordinary skill would be motivated to test multiple

compounds because both, the CREB pathway and NPY have known cognitive modulatory effects.” Even if the Examiner’s statements on page 5 of the Office Action, are correct there is no logical basis for the jump from those statements to the Examiner’s conclusion. That certain compounds have known functions does not render obvious specific methods of screening compounds for such functions. Again, the Examiner puts forth an ungrounded, unsupportable statement as the basis for the rejection – this is simply impermissible. As previously stated by Applicants, Sheriff does not teach or suggest screening a plurality of compounds for potential development as candidate cognitive enhancer compounds by determining the ability of said candidate cognitive enhancer compounds to enhance cyclic adenosine monophosphate (cAMP) response element binding protein (CREB) pathway and identifying said test compound as a candidate cognitive enhancer based on the selection parameters of the pending claims.

The Examiner cites *In re McLaughlin*, 443 F.2d 1392, 1395 (C.C.P.A. 1971), for the proposition that “any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicants own disclosure, such a reconstruction is proper.” This statement is correctly quoted, but inapposite to the present facts. As Applicants set forth above, the Examiner has not identified any reason why the prior art teaches or suggests testing “a plurality of test compounds.” The only place such a disclosure is found is in Applicants’ claim. As held by *McLaughlin*, that is a wholly inappropriate source. *See id.*

The Examiner also notes that the “plurality of test compounds” language is in the preamble and that the language is redundant to the body of the claim because “screening implies testing more than one compound.” OA, page 6-7. Under the Examiner’s reasoning, testing a plurality of test compounds is a limitation of the claims because screening requires such testing. This position, in fact, supports the Applicants’ position that Shariff and Herzog do not support a *prima facie* case of obviousness.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejections of claims 1, 3-7, 9-12, 14 and 16 under 35 U.S.C. § 103 based on Sheriff in view of Herzog.

B. Sheriff in View of Herzog and in further view of Barad – Claims 19(a-k) and 20-24

Claims 19(a-k) and 20-24 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Sheriff in view of Herzog and in further view of Barad et al., PNAS 95: 15020-15025, 1998 (“Barad”) “for reasons of record in the Office Action dated 17 April 2008.” OA, page 7. Applicants respectfully traverse for the reasons set forth herein and the reasons set forth in their reply dated July 17, 2008, which is hereby incorporated by reference.

Applicants maintain their prior arguments. Applicants also incorporate their arguments above and note that neither Sheriff nor Herzog teaches or suggests screening a plurality of compounds to determine the ability of the compounds to enhance the cyclic adenosine monophosphate (cAMP) response element binding protein (CREB) pathway and identifying the compounds as a candidate cognitive enhancer compound based on the selection parameters of the pending claims. Barad does not remedy these deficiencies of Sheriff and Herzog.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejections of claims 19(a-k) and 20-24 under 35 U.S.C. § 103 as allegedly obvious over Sheriff in view of Herzog and in further view of Barad.

C. Sheriff in View of Herzog and in further view of Barad – Claims 2, 8 and 13

Claims 2, 8 and 13 stand rejected under 35 U.S.C. § 103 as allegedly obvious over Sheriff in view of Herzog and in further view of Barad “for reasons of record in the Office Action dated 17 April 2008.” OA, page 8. Applicants respectfully traverse for the reasons set forth herein and the reasons set forth in their reply dated July 17, 2008, which is hereby incorporated by reference.

Applicants maintain their prior arguments. Applicants also incorporate their arguments above and note that neither Sheriff nor Herzog teaches or suggests screening a plurality of compounds to determine the ability of the compounds to enhance the cyclic adenosine monophosphate (cAMP) response element binding protein (CREB) pathway and identifying the compounds as a candidate cognitive enhancer compound based on the selection parameters of the pending claims. Barad does not remedy these deficiencies of Sheriff and Herzog.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejections of claims 2, 8 and 13 under 35 U.S.C. § 103 as allegedly obvious over Sheriff in view of Herzog and in further view of Barad.

CONCLUSION

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account

Respectfully submitted,



Don J. Pelto
Reg. No. 33,754

Date: **December 29, 2008**

Sheppard Mullin Richter & Hampton LLP
1300 I Street NW
Eleventh Floor East
Washington, D.C. 20005
Tel: (202) 772-5362
Fax: (202) 312-9415